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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/646,270 | 08/22/2003 | Rong-Tsun Wu | SIPT121648 | 9640 |
| 26389 7590 01/08/2007 CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800 SEATTLE, WA 98101-2347 | | | EXAMINER | |
| | | | FLOOD, MICHELE C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1655 | |
| | | | | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 31 DAYS | | 01/08/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| , , | Application No. | Applicant(s) | | | | |
|---|---|---------------|--|--|--|--|
| | 10/646,270 | WU, RONG-TSUN | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Michele Flood | 1655 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 14 September 2006. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-23 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) 1-23 are subject to restriction and/or election requirement. Application Papers 9) □ The specification is objected to by the Examiner. 10) □ The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa | ite | | | | |

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DETAILED ACTION

Applicant's election without traverse of the species liver cirrhosis, in the reply filed on September 14, 2006 is acknowledged. Review of the claims finds that further restriction of the claims is necessary, as set forth below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to an extract product from the root of *Polygonum multiflorum* Thunb., which is prepared from a process comprising the steps of: (a) subjecting a suitable amount of a starting root material of *Polygonum multiflorum* Thunb. to a freezing treatment for a period of time; (b) subjecting a frozen product obtained in step (a) to an extraction treatment with methanol; (c) subjecting a resultant product from step (b) to a separating treatment to obtain a methanol solution free of extracted root debris of the starting root material of *Polygonum multiflorum* Thunb.; and (d) removing methanol from the methanol solution obtained in step (c) to obtain a methanol-extracted product, classified in class 424, subclass 773 or class 514, subclass 838, for example.
- II. Claims 12-22, drawn to a process for preparing an extract product from the root of *Polygonum multiflorum* Thunb., comprising the steps of: (a) subjecting a suitable amount of a starting root material of *Polygonum*

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multiflorum Thunb. to a freezing treatment for a period of time; (b) subjecting a frozen product obtained in step (a) to an extraction treatment with methanol; (c) subjecting a resultant product from step (b) to a separating treatment to obtain a methanol solution free of extracted root debris of the starting root material of *Polygonum multiflorum* Thunb.; and (d) removing methanol from the methanol solution obtained in step (c) to obtain a methanol-extracted product, classified in class 435, subclass 6, for example.

III. Claim 23, drawn to a pharmaceutical composition comprising an extract product from the root of *Polygonum multiflorum* Thunb. prepared by a process according to any one of Claims 12-22, classified in class 424, subclass 773, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I and Invention II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the invention of Group I is directed to a methanol-extracted product prepared by claim-designated process steps of (a) – (d), whereas the invention of Group II is directed to a process for preparing a methanol-extracted product comprising claim-designated process steps of (a) - (d), which are further defined specified temperature ranges, experimental parameters and process steps not required in the making of the product-by-process of Invention I.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process, as evidenced by the claims themselves.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to different products prepared by different process steps. Different products prepared by different process are not expected to have the same functional effect.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: The pharmaceutical compositions of Claims 5-11. The species are independent or distinct because the pharmaceutical compositions of Claims 5-11 are directed to pharmaceutical compositions having widely divergent functional effects for the treatment of broadly divergent and different disease conditions.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-4, 12 and 23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood Primary Examiner Art Unit 1655

MCF

November 27, 2006